

EXHIBIT B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA, *ex rel.*
JULIE LONG,

Plaintiffs,

v.

JANSSEN BIOTECH, INC.,

Defendant.

Civil Action No. 16-CV-12182-FDS

**DEFENDANT JANSSEN BIOTECH, INC.'S AMENDED WRITTEN RESPONSES TO
RELATOR'S MAY 6, 2024 30(b)(6) DEPOSITION NOTICE**

Defendant Janssen Biotech, Inc. ("Janssen" or "Defendant") provides the following objections and responses to Relator's Notice of Deposition pursuant to Federal Rule of Civil Procedure 30(b)(6) (the "Notice"), dated May 6, 2024.

GENERAL OBJECTIONS

1. Janssen objects to each Topic set forth in the Notice to the extent that it calls for information protected from disclosure by the attorney-client privilege, the protection afforded work product, or any other applicable privilege or protection. As previously stated, Janssen has not asserted and does not intend to assert the advice of counsel defense.

2. Janssen objects to each Topic to the extent it is vague and ambiguous, or fails to state with "reasonable particularity the matters for examination" as required by Rule 30(b)(6) of the Federal Rules of Civil Procedure.

3. Janssen objects to each Topic to the extent that it seeks information not relevant to any claim, counterclaim, or defense pled by any party in this action.

4. Janssen objects to each Topic to the extent that it is overly broad and unduly burdensome and not proportional to the needs of the case, and thus exceeds the scope of discoverable matters under Fed. R. Civ. P. 26.

5. Janssen objects to each Topic to the extent that it calls for information that is confidential or proprietary to Janssen. To the extent that Janssen provides such information, it will do so pursuant to the terms of the Protective Order entered in this case on March 11, 2021.

6. Janssen objects to each Topic to the extent it purports to impose any obligation on Janssen to locate, obtain, and/or provide testimony or documents regarding information not in the possession, custody, or control of Janssen.

7. Janssen objects to each Topic to the extent it seeks to impose obligations or requirements on Janssen which are greater than or different from those imposed by the Federal Rules of Civil Procedure and/or any other applicable law, rule, or regulation.

8. Janssen objects to any implications and to any explicit or implicit characterization of facts, events, circumstances, or issues set forth in the Notice. Any response by Janssen is not intended to indicate that Janssen agrees with any implications or any explicit or implicit characterization of facts, events, circumstances, or issues in the Notice, or that such implications or characterizations are relevant to this action.

9. Janssen objects to each Topic set forth in the Notice to the extent it seeks information outside of the scope authorized by the Court. Specifically, Janssen objects to each Topic to the extent it seeks information outside the scope of phased discovery authorized by the Court on December 14, 2020 and in subsequent orders, including to the extent it seeks information that is not related to services provided during Relator's employment as an ABS at Janssen to the physician practices specifically alleged in the Second Amended Complaint.

10. Janssen's responses are made without waiving or intending to waive in any way (a) any objections as to competency, relevancy, materiality, privilege and/or admissibility, or subject matter thereof, in any subsequent proceeding in this or any other action; (b) the right to object on any ground to the use of these responses, or the subject matter thereof, in any subsequent proceeding in this or any other action; (c) the right to object to a demand for further responses to these or any other discovery involving or related to the subject matter of these topics; and (d) the right to object on any ground to these or any other or future discovery responses.

SPECIFIC OBJECTIONS AND RESPONSES

TOPIC NO. 1:

For each Program (or its substantive equivalent), the following information:

- (a) When You started providing the Program to IOI Customers.
- (b) When You stopped providing the Program to IOI Customers.
- (c) Whether the Program was branded or unbranded.
- (d) Whether You provided the Program to all physician practices that prescribed Remicade and/or Simponi ARIA or only to targeted physician practices.
- (e) The factors that were considered in determining which physician practices received the Program.
- (f) Whether You paid a vendor or Outside Consultant to develop the Program and the approximate amount You paid the vendor or Outside Consultant to develop the Program.
- (g) Whether the Program was provided to IOI Customers in person and/or remotely by an ABS.
- (h) Whether You paid an Outside Consultant to provide the Program to IOI Customers in person and/or remotely and the amount You paid for the presentation of the Program.

(i) Whether You had ABSs in the Oncology division provide the Program (or substantive equivalent) to oncology practices.

(j) All Your purposes and objectives in providing the Program to IOI Customers.

(k) The amount You charged IOI Customers for the Program.

(l) The actions You took to evaluate the benefit or value, including the independent value, that IOI Customers received from the Program.

(m) Your belief and knowledge concerning the benefit and/or value, including the independent value, that IOI Customers received from the IOI Support, the bases for such belief. Included in this topic are the results of any assessments or analyses You performed to review or determine the benefit or value, including the independent value, that IOI Customers received from the IOI Support.

(n) Your knowledge concerning the prescriptions and infusions of Remicade and/or Simponi ARIA to patients including Medicare patients that resulted from and/or were influenced by Your provision of the Program to IOI Customers. Included in this topic are the results of any assessments or analyses You performed concerning whether receiving the Program caused, impacted, or influenced the recipient to prescribe and/or utilize Remicade and/or Simponi ARIA.

(o) Whether you advertised to physicians and patients that you provided the Program to IOI Customers.

(p) All actions You took to determine whether providing the Program to IOI Customers violated the AKS and/or FCA.

(q) Whether the Program was reviewed by Your legal department separate and apart from any review conducted by an attorney in connection with a Promotional Review Committee (or

equivalent committee) review. Included in this topic are the review process, the approximate dates of the reviews, and persons from the legal department who performed the reviews.

(r) Your belief and knowledge concerning whether providing the Program to IOI Customers violated the AKS and the bases for such belief.

Relevant time period: Except for 1(b), from the creation of the Program to until February 19, 2016. For 1(b), from the creation of the Program to until the present.

RESPONSE TO TOPIC NO. 1:

Janssen objects to this Topic, including each subtopic, to the extent that it is overly broad and unduly burdensome, not proportional to the needs of the case, and exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic, including each subtopic, to the extent it is cumulative and seeks information that is duplicative of what is contained in the documents or written discovery that Janssen has already produced. Janssen specifically objects that subtopics (a), (b), (c), (g), (j), (l), (m), (n), (p), (q), and (r) seek information that is cumulative or duplicative of information and documents that have been provided in response to Relator's past discovery requests.

Janssen further objects to this Topic, including each subtopic, on the ground that it is vague, ambiguous, and overbroad and does not describe with reasonable particularity the matters on which examination is requested as required by Fed. R. Civ. P. 30(b)(6). For example, Janssen objects to the following terms, which are not defined terms, are overbroad, and are reasonably subject to multiple interpretations:

- The term "substantive equivalent" in the general topic and in subtopic (i);
- The term "[a]ll [y]our purposes and objectives" in subtopic (j);
- The terms "benefit" and "value" in subtopics (l) and (m);

- The term “assessments or analyses” in subtopics (m) and (n); and,
- The term “advertised” in subtopic (o).

Further, by its terms, subtopic (e) seeks testimony about factors considered by all individuals and entities within and outside of Janssen in determining whether to provide the programs at issue, including individual ABSs and third party physicians. No witness could reasonably be prepared to testify on this Topic at a high level of detail, and Janssen will not provide a witness to do so here.

Further, by its terms, subtopic (j) seeks testimony about the purposes and objectives underlying each of the individual programs at issue. No witness could reasonably be prepared to testify on this Topic at a high level of detail, and Janssen will not provide a witness to do so here.

Janssen further objects to subtopic (k) to the extent that it is premised on the assumption that customers were charged for the programs at issue.

Janssen further objects to subtopics (l) and (m) to the extent that they are premised on the assumption that the programs at issue had independent value to customers, or that Janssen conducted formal or informal analyses of the value received by customers from those programs.

Janssen further objects that subtopic (i) seeks information that is irrelevant and/or unrelated to the facts at issue in this case, and which would be unduly burdensome to provide. Relator’s Second Amended Complaint does not include any allegations about Janssen’s Oncology division. Further, Phase 1 discovery is limited to testing the claims for which Relator has direct knowledge – “her claims, what she did, what her managers were or told her to do, information she got from people at a national level, if she got any, [and] what happened with these . . . accounts.” December 14, 2020 Hr’g Tr. at 10:8-11. Any attempt to further amend the complaint to add such allegations would be outside the scope of Phase 1, as set by Judge Saylor.

Janssen further objects to subtopics (l), (m), (p), (q), and (r) to the extent they seek information protected from disclosure by the attorney-client privilege or the protection afforded work product. It is difficult, for example, to discern what non-privileged information Relator seeks to elicit from Topic 1(r)—“Your belief and knowledge concerning whether providing the Program to IOI Customers violated the AKS and the bases for such belief.” Information concerning legal review and legal opinions is privileged and is not subject to 30(b)(6) testimony. Further, such legal opinions are irrelevant, as Janssen is not asserting the advice of counsel defense, relying on privileged legal advice, or asserting any defense based on its subjective good faith belief that the programs were legal. Rather than move to quash in advance, Janssen will put forth a witness on these topics to answer questions about non-privileged information. But, for avoidance of doubt, to the extent Relator asks questions about privileged information, Janssen will instruct the witness not to answer.

Subject to and without waiving the foregoing objections, Janssen will provide a written response to questions concerning subtopics (a), (b), (c), (d),(f), (g), (h), and (k). Janssen will provide a witness to testify on all other subtopics.

TOPIC NO. 2:

For the IOI Support as a whole, the following information:

- (a) Whether You provided the IOI Support to all physician practices that prescribed Remicade and/or Simponi ARIA or only to targeted physician practices.
- (b) The factors that were considered in determining which physician practices received the IOI Support.
- (c) All Your purposes and objectives in providing the IOI Support to IOI Customers.

(d) The amounts You spent each year providing the IOI Support to IOI Customers (through ABSs and Outside Consultants) and Your return on investment concerning the provision of the IOI Support to IOI Customers.

(e) The amount You charged IOI Customers for the IOI Support.

(f) The actions You took to evaluate the benefit or value, including the independent value, that IOI Customers received from the IOI Support.

(g) Your belief and knowledge concerning the benefit and/or value, including the independent value, that IOI Customers received from the IOI Support, the bases for such belief. Included in this topic are the results of any assessments or analyses You performed to review or determine the benefit or value, including the independent value, that IOI Customers received from the IOI Support.

(h) Your knowledge concerning the prescriptions and infusions of Remicade and/or Simponi ARIA to patients including Medicare patients that resulted from and/or were influenced by Your provision of the IOI Support to IOI Customers. Included in this topic are the results of any assessments or analyses You performed concerning whether receiving the IOI Support caused, impacted, or influenced the recipient to prescribe and/or utilize Remicade and/or Simponi ARIA.

(i) Whether You advertised to physicians and patients that you provided the IOI Support to IOI Customers.

(j) All actions You took to determine whether providing the IOI Support and Programs to IOI Customers violated the AKS and/or FCA.

(k) Whether the provision of the IOI Support to IOI Customers was reviewed by Your legal department separate and apart from any review conducted by an attorney in connection

with a Promotional Review Committee (or equivalent committee) review. Included in this topic are the review process, the approximate dates of the reviews, and persons from the legal department who performed the reviews.

(l) Your belief and knowledge concerning whether providing the IOI Support to IOI Customers violated the AKS and the bases for such belief.

Relevant time period: From the creation of the strategy to provide the IOI Support to IOI Customers to until February 19, 2016.

RESPONSE TO TOPIC NO. 2:

Janssen objects to this Topic, including each subtopic, to the extent that it is overly broad and unduly burdensome, not proportional to the needs of the case, and exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic, including each subtopic, to the extent it is cumulative and seeks information that is duplicative of what is contained in the documents or written discovery that Janssen has already produced. Janssen specifically objects that subtopics (c), (f), (g), (h), (j), (k), and (l) seek information that is likely to be cumulative or duplicative of information and documents that have been provided in response to Relator's past discovery requests.

Janssen further objects to this Topic, including each subtopic, on the ground that it is vague, ambiguous, and overbroad and does not describe with reasonable particularity the matters on which examination is requested as required by Fed. R. Civ. P. 30(b)(6). For example, Janssen objects to the following terms, which are not defined terms, are overbroad, and are reasonably subject to multiple interpretations:

- The term "[a]ll [y]our purposes and objectives" in subtopic (c);
- The term "return on investment" in subtopic (d);

- The terms “benefit” and “value” in subtopics (g) and (h);
- The term “assessments or analyses” in subtopics (g) and (h); and,
- The term “advertised” in subtopic (i).

Further, by its terms, subtopic (b) seeks testimony about factors considered by all individuals and entities within and outside of Janssen in determining whether to provide the programs at issue, including individual ABSs and third party physicians. No witness could reasonably be prepared to testify on this Topic at a high level of detail, and Janssen will not provide a witness to do so here.

Further, by its terms, subtopic (c) seeks testimony about the purposes and objectives underlying each of the individual programs at issue. No witness could reasonably be prepared to testify on this Topic at a high level of detail, and Janssen will not provide a witness to do so here.

Further, by its terms, subtopic (d) seeks amounts spent on all aspects of the programs at issue, which could be construed to include incidental costs and individualized salary information over the entirety of the time period identified. No witness could reasonably be prepared to testify on this Topic at a high level of detail, and Janssen will not provide a witness to do so here.

Janssen further objects to subtopic (e) to the extent that it is premised on the assumption that customers were charged for the programs at issue.

Janssen further objects to subtopics (f) and (g) to the extent that they are premised on the assumption that the programs at issue had independent value to customers, or that Janssen conducted formal or informal analyses of the value received by customers from those programs.

Janssen further objects to subtopics (j), (k), and (l) to the extent they seek information protected from disclosure by the attorney-client privilege or the protection afforded work product. Information concerning legal review and legal opinions is privileged and is not subject to 30(b)(6) testimony. Further, such legal opinions are irrelevant, as Janssen is not asserting the

advice of counsel defense, relying on privileged legal advice, or asserting any defense based on its subjective good faith belief that the programs were legal..

Subject to and without waiving the foregoing objections, Janssen will provide a written response to questions concerning subtopics (a), (d), and (e). Janssen will provide a witness to testify on all other subtopics.

TOPIC NO. 3:

Your methods and practices for tracking and/or recording the following information concerning the Programs provided to IOI Customers:

(a) When an ABS or Outside Consultant provided advice, education, or assistance to a health care provider or his/her staff concerning opening an IOI within a physician practice.

(b) When an ABS or Outside Consultant provided a Program to an IOI Customer.

(c) The persons from IOI Customers who attended a Program.

(d) The benefit and/or value, including the independent value, of a Program to the recipient.

(e) The amount You spent providing the Program and/or IOI Support (through ABSs and Outside Consultants).

(f) The return You received from providing the Program and/or IOI Support.

Relevant time period: From when You began providing the IOI Support and Programs to IOI Customers to until February 19, 2016.

RESPONSE TO TOPIC NO. 3:

Janssen objects to this Topic, including each subtopic, to the extent that it is overly broad and unduly burdensome, not proportional to the needs of the case, and exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic, including each subtopic, to the extent it is cumulative and seeks information that is duplicative of what is contained in the documents or written discovery that Janssen has already produced. Janssen specifically objects that this Topic, including all subtopics, seeks information that is likely to be cumulative or duplicative of information and documents that have been provided in response to Relator's past discovery requests.

Janssen further objects to this Topic, including each subtopic, on the ground that it is vague, ambiguous, and overbroad and does not describe with reasonable particularity the matters on which examination is requested as required by Fed. R. Civ. P. 30(b)(6). For example, Janssen objects to the following terms, which are not defined terms, are overbroad, and are reasonably subject to multiple interpretations:

- The term "advice, education, or assistance" in subtopic (a);
- The terms "benefit" and "value" in subtopic (d); and,
- The term "return" in subtopic (f).

Janssen further objects to subtopic (a) to the extent that it is premised on the assumption that Janssen ABSs provided advice, education, or assistance to physician practices in opening IOIs beyond the PRC-approved content of presentations at issue in this case.

Janssen further objects to subtopic (d) to the extent that it is premised on the assumption that the programs at issue had independent value to customers, or that Janssen conducted formal or informal analyses of the value received by customers from those programs.

Subject to and without waiving the foregoing objections, Janssen will provide a witness to testify on this Topic, including all subtopics.

TOPIC NO. 4:

Your knowledge and understanding concerning (a) the AKS, (b) the safe harbor regulations, and (c) the Office of Inspector General for the U.S. Department of Health and Human Services's guidance concerning the provision of product-related services to customers.

Relevant time period: From the creation of the strategy to provide the IOI Support to IOI customers to until February 19, 2016.

RESPONSE TO TOPIC NO. 4:

Janssen objects to this Topic to the extent that it is overly broad and unduly burdensome, not proportional to the needs of the case, and exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic to the extent it is cumulative and seeks information that is duplicative of what is contained in the documents or written discovery that Janssen has already produced.

Janssen further objects to this Topic on the ground that it is vague, ambiguous, and overbroad and does not describe with reasonable particularity the matters on which examination is requested as required by Fed. R. Civ. P. 30(b)(6). For example, the term "product-related services" is not a defined term, is overbroad, and is reasonably subject to multiple interpretations. Further, by its terms, this Topic seeks testimony about the entirety of Janssen's knowledge of all OIG guidance concerning the identified topic, potentially encompassing both formal and informal guidance materials throughout the time period at issue. No witness could reasonably be prepared to testify on this Topic at a high level of detail, and Janssen will not provide a witness to do so here.

Janssen further objects to this Topic to the extent it seeks information protected from disclosure by the attorney-client privilege or the protection afforded work product. Janssen's

understanding of relevant statutes and regulations based on confidential legal advice is privileged and is not subject to 30(b)(6) testimony. Further, such legal opinions are irrelevant, as Janssen is not asserting the advice of counsel defense, relying on privileged legal advice, or asserting any defense based on its subjective good faith belief that the programs were legal.

Subject to and without waiving the foregoing objections, Janssen will provide a witness to testify on this Topic.

TOPIC NO. 5:

The actions You took to train Your employees who were responsible for evaluating the legality of providing the IOI Support concerning conduct prohibited by the AKS, including the provision of services that have independent value to customers.

Relevant time period: From the creation of the strategy to provide the IOI Support to IOI Customers to until February 19, 2016.

RESPONSE TO TOPIC NO. 5:

Janssen objects to this Topic to the extent that it is overly broad and unduly burdensome, not proportional to the needs of the case, and exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic to the extent it is cumulative and seeks information that is duplicative of what is contained in the documents or written discovery that Janssen has already produced.

Janssen further objects to this Topic on the ground that it is vague, ambiguous, and overbroad and does not describe with reasonable particularity the matters on which examination is requested as required by Fed. R. Civ. P. 30(b)(6). For example, the term “services that have independent value to customers” is not a defined term, is overbroad, and is reasonably subject to multiple interpretations. Further, by its terms, this Topic seeks testimony about the training of all

employees with relevant responsibilities throughout the time period at issue. No witness could reasonably be prepared to testify on this Topic at a high level of detail, and Janssen will not provide a witness to do so here.

Janssen further objects to this Topic to the extent it seeks information protected from disclosure by the attorney-client privilege or the protection afforded work product, including any confidential evaluations of the legality of the programs at issue provided by counsel. Information concerning legal review and legal opinions is privileged and is not subject to 30(b)(6) testimony. Further, such opinions are irrelevant, as Janssen is not asserting the advice of counsel defense, relying on privileged legal advice, or asserting any defense based on its subjective good faith belief that the programs were legal..

Janssen further objects to this Topic to the extent it is premised on the assumption that the programs at issue had independent value to customers, or that Janssen conducted formal or informal analyses of the value received by customers from those programs.

Subject to and without waiving the foregoing objections, Janssen will provide a witness to testify on this Topic.

TOPIC NO. 6:

Whether any of Your employees or agents advised or expressed a concern or belief that Your provision of the IOI Support and/or Programs to IOI Customers violated: (a) the law including the AKS and/or FCA, and/or (b) Your compliance policies concerning the provision of consulting, product-related services, and/or educational services to customers.

Relevant time period: From the creation of the strategy to provide the IOI Support to IOI Customers to until February 19, 2016.

RESPONSE TO TOPIC NO. 6:

Janssen objects to this Topic to the extent that it is overly broad and unduly burdensome, not proportional to the needs of the case, and exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic on the ground that it is vague, ambiguous, and overbroad and does not describe with reasonable particularity the matters on which examination is requested as required by Fed. R. Civ. P. 30(b)(6). For example, the terms “concern,” “consulting,” “product-related services,” and “educational services” are not defined terms, are overbroad, and are reasonably subject to multiple interpretations.

Janssen further objects to this Topic to the extent it seeks information protected from disclosure by the attorney-client privilege or the protection afforded work product, including any confidential evaluations of the legality of the programs at issue provided by counsel. Information concerning legal review and legal opinions is privileged and is not subject to 30(b)(6) testimony. Further, such legal opinions are irrelevant, as Janssen is not asserting the advice of counsel defense, relying on privileged legal advice, or asserting any defense based on its subjective good faith belief that the programs were legal..

Subject to and without waiving the foregoing objections, Janssen will provide a witness to testify on this Topic.

TOPIC NO. 7:

All legal actions that You have settled and/or a judgment or verdict was entered against You in which it was alleged that You violated the AKS.

RESPONSE TO TOPIC NO. 7:

Janssen objects to this Topic to the extent that it is overly broad and unduly burdensome, not proportional to the needs of the case, and exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic to the extent that it seeks information that is irrelevant and/or unrelated to the facts at issue in this case.

Janssen further objects to this Topic to the extent it is cumulative and seeks information that is duplicative of what is contained in the documents or written discovery that Janssen has already produced, or that is publicly available.

Janssen further objects to this Topic to the extent it seeks information about legal actions that took place more than ten years before the filing of this case as irrelevant and unduly burdensome. Janssen will not provide a witness to testify on legal actions that were resolved before October of 2006.

Janssen further objects to this Topic on the ground that it is vague, ambiguous, and overbroad and does not describe with reasonable particularity the matters on which examination is requested as required by Fed. R. Civ. P. 30(b)(6). For example, the term “legal actions” is not a defined term, is overbroad, and is reasonably subject to multiple interpretations. For purposes of this Topic, Janssen construes this term to refer to lawsuits filed in federal or state court in the United States within the time period identified.

Subject to and without waiving the foregoing objections, Janssen will provide a witness to testify on this Topic within the constraints identified above..

TOPIC NO. 8:

Your asserted belief that You acted in good faith when providing the IOI Support to IOI Customers and the asserted bases for this belief.

RESPONSE TO TOPIC NO. 8:

Janssen objects to this Topic to the extent that it is overly broad and unduly burdensome, not proportional to the needs of the case, and exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic to the extent it is cumulative and seeks information that is duplicative of what is contained in the documents or written discovery that Janssen has already produced.

Janssen further objects to this Topic on the ground that it is vague, ambiguous, and overbroad and does not describe with reasonable particularity the matters on which examination is requested as required by Fed. R. Civ. P. 30(b)(6). For example, the term “asserted bases for this belief” is not a defined term, is overbroad, and is reasonably subject to multiple interpretations. For purposes of this Topic, Janssen construes this term to refer to its affirmative defense that all actions taken by Janssen with respect to any of the matters alleged by Relator were taken in good faith and in accordance with established industry practice.

Janssen further objects to this Topic to the extent it seeks information protected from disclosure by the attorney-client privilege or the protection afforded work product, including any confidential evaluations of the legality of the programs at issue provided by counsel.

Information concerning legal review and legal opinions is privileged and is not subject to 30(b)(6) testimony. Further, such legal opinions are irrelevant, as Janssen is not asserting the advice of counsel defense, relying on privileged legal advice, or asserting any defense based on its subjective good faith belief that the programs were legal.

Subject to and without waiving the foregoing objections, Janssen will provide a witness to testify on this Topic.

TOPIC NO. 9:

The Federal Government's investigation(s) referenced in Your answer to Interrogatory 15 and any findings and/or determinations that the Federal Government communicated to You in connection with the Federal Government's investigation(s).

RESPONSE TO TOPIC NO. 9:

Janssen objects to this Topic to the extent that it is overly broad and unduly burdensome, not proportional to the needs of the case, and exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic to the extent that it seeks information that is irrelevant and/or unrelated to the facts at issue in this case.

Janssen further objects to this Topic to the extent it is cumulative and seeks information that is duplicative of what is contained in the documents or written discovery that Janssen has already produced.

Janssen further objects to this Topic on the ground that it is vague, ambiguous, and overbroad and does not describe with reasonable particularity the matters on which examination is requested as required by Fed. R. Civ. P. 30(b)(6). For example, the terms "findings" and "determinations" are not defined terms, are overbroad, and are reasonably subject to multiple interpretations. Further, it would not be possible to prepare a witness to testify generally on all aspects of the investigations identified in this Topic. For purposes of this Topic, Janssen construes this Topic to seek testimony on the high level subject matter and timeline of the investigation(s) at issue and any findings or determinations that the Federal Government communicated to Janssen in connection with the investigation. .

Subject to and without waiving the foregoing objections, Janssen will provide a witness to testify on this Topic.

TOPIC NO. 10 :

Your reasons for not reporting the IOI Support and/or Programs that were provided to IOI Customers to the Centers for Medicare & Medicaid Services under 42 C.F.R. § 403.904 and 42 U.S.C. § 1320a-7h, including identification of the individuals who made the decision(s) to not report the IOI Support and/or Programs that were provided to IOI Customers to Centers for Medicare & Medicaid Services.

Relevant time period: From Your first report to the Centers for Medicare & Medicaid Services under 42 C.F.R. § 403.904 and 42 U.S.C. § 1320a-7h to until February 19, 2016.

RESPONSE TO TOPIC NO. 10:

Janssen objects to this Topic to the extent that it is overly broad and unduly burdensome, not proportional to the needs of the case, and exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic to the extent that it seeks information that is irrelevant and/or unrelated to the facts at issue in this case.

Janssen further objects to this Topic to the extent it seeks information protected from disclosure by the attorney-client privilege or the protection afforded work product, including any confidential evaluations of the legality of the programs at issue provided by counsel. Information concerning legal review and legal opinions is privileged and is not subject to 30(b)(6) testimony. Further, such legal opinions are irrelevant, as Janssen is not relying on privileged information and does not intend to assert the advice of counsel defense.

Subject to and without waiving the foregoing objections, Janssen will provide a witness to testify on this Topic.

TOPIC NO. 11:

Your compliance policy and/or guidance document (and equivalents thereof) concerning the topics of (i) providing consulting and/or services to customers (see, e.g., JANSSENBIO-037-00000844 (Guidance Doc. 2); JANSSENBIO-018-00000067; JANSSENBIO-031-00016550; JANSSENBIO-045-00000537 (Ch. 14)), (ii) providing reimbursement information and services to customers (see, e.g., JANSSENBIO-008-00000777 (Guidance Doc. 25); JANSSENBIO-031-00016546; JANSSENBIO-018-00001010; JANSSENBIO-064-00003344; JANSSENBIO-045-00000537 (Ch. 13)), and/or (iii) providing educational support and/or programs to customers (see, e.g., JANSSENBIO-037-00001252; JANSSENBIO-055-00004234; JANSSENBIO-031-00016492) that was in effect at any time during the period 2001 to February 2020.

RESPONSE TO TOPIC NO. 11:

Janssen objects to this Topic to the extent that it is overly broad and unduly burdensome, not proportional to the needs of the case, and exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic to the extent it is cumulative and seeks information that is duplicative of what is contained in the documents or written discovery that Janssen has already produced.

Janssen further objects to this Topic on the ground that it is vague, ambiguous, and overbroad and does not describe with reasonable particularity the matters on which examination is requested as required by Fed. R. Civ. P. 30(b)(6). For example, the term “equivalents thereof” is not a defined term, is overbroad, and is reasonably subject to multiple interpretations. Further, by its terms, this Topic seeks testimony about every aspect of compliance policy or guidance document related to the identified topics, for a period of almost two decades. No witness could

reasonably be prepared to testify on this Topic at a high level of detail, and Janssen will not provide a witness to do so here.

Subject to and without waiving the foregoing objections, Janssen will provide a witness to testify on this Topic.

TOPIC NO. 12:

The reasons why You revised or replaced the compliance policy and/or guidance document concerning the provision of consulting and product-related services in 2015. See, e.g., JANSSENBIO-064-00003167.

RESPONSE TO TOPIC NO. 12:

Janssen objects to this Topic to the extent it is cumulative and seeks information that is duplicative of what is contained in the documents or written discovery that Janssen has already produced.

Janssen further objects to this Topic to the extent that it seeks information that is irrelevant and unrelated to the facts at issue in this case.

Subject to and without waiving the foregoing objections, Janssen will provide a witness to testify on this topic.

TOPIC NO. 13 (as amended June 24, 2024):

The development and approval of the strategy to provide the IOI Support and Programs to IOI Customers, including the approval(s) to continue engaging in the strategy.

Relevant time period: From the creation of the strategy to provide the IOI Support and Programs to IOI Customers to until February 19, 2016.

RESPONSE TO TOPIC NO. 13:

Janssen objects to this Topic to the extent that it is overly broad and unduly burdensome, not proportional to the needs of the case, and exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic to the extent it is cumulative and seeks information that is duplicative of what is contained in the documents or written discovery that Janssen has already produced.

Janssen further objects to this Topic on the ground that it is vague, ambiguous, and overbroad and does not describe with reasonable particularity the matters on which examination is requested as required by Fed. R. Civ. P. 30(b)(6). For example, the terms “strategy” and “approvals” are not defined terms, are overbroad, and are reasonably subject to multiple interpretations. By its terms, this Topic seeks testimony about every aspect of the “strategy” underlying the programs at issue in this case, for a period of almost two decades. No witness could reasonably be prepared to testify on this Topic at a high level of detail, and Janssen will not provide a witness to do so here.

Subject to and without waiving the foregoing objections, Janssen will provide a witness to testify on this Topic.

TOPIC NO. 14 (as amended June 24, 2024):

An explanation of the infusion business model, IOI business model, and/or Remicade business model that You promoted to IOI Customers.

Relevant time period: From the creation of the strategy to provide the IOI Support to IOI Customers to until February 19, 2016.

RESPONSE TO TOPIC NO. 14:

Janssen objects to this Topic to the extent that it is overly broad and unduly burdensome, not proportional to the needs of the case, and exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic to the extent it is cumulative and seeks information that is duplicative of what is contained in the documents or written discovery that Janssen has already produced.

Janssen further objects to this Topic on the ground that it is vague, ambiguous, and overbroad and does not describe with reasonable particularity the matters on which examination is requested as required by Fed. R. Civ. P. 30(b)(6). For example, the terms “infusion business model,” “IOI business model,” and “Remicade business model” are not defined terms, are overbroad, and are reasonably subject to multiple interpretations. Further, by its terms, this Topic seeks testimony about every aspect of the “business model” underlying the programs at issue in this case, for a period of almost two decades. No witness could reasonably be prepared to testify on this Topic at a high level of detail, and Janssen will not provide a witness to do so here.

Janssen further objects to this Topic to the extent it is are premised on the assumption that the “promoted” the identified “business models” to customers.

Subject to and without waiving the foregoing objections, Janssen will provide a witness to testify on this Topic.

TOPIC NO. 15:

Why You transferred responsibility for the Site of Care field team including ABSs from Immunology Sales to Immunology Marketing in 2015.

RESPONSE TO TOPIC NO. 15:

Janssen objects to this Topic to the extent that it seeks information that is irrelevant and/or unrelated to the facts at issue in this case.

Subject to and without waiving the foregoing objections, Janssen will provide a witness to testify on this Topic.

TOPIC NO. 16:

Your compensation system for ABSs including sales bonuses and contests and the Management By Objective (MBO) system and bonuses.

Relevant time period: From the creation of the strategy to provide the IOI Support to IOI Customers to until February 19, 2016.

RESPONSE TO TOPIC NO. 16:

Janssen objects that this Topic is overly broad, unduly burdensome, not proportional to the needs of the case, and exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic to the extent it is cumulative and seeks information that is duplicative of what is contained in the documents or written discovery that Janssen has already produced.

Janssen further objects to this Topic on the ground that it is vague, ambiguous, and overbroad and does not describe with reasonable particularity the matters on which examination is requested as required by Fed. R. Civ. P. 30(b)(6). For example, the terms “compensation system,” “sales bonuses,” and “contests” are not defined terms, are overbroad, and are reasonably subject to multiple interpretations. Further, by its terms, this Topic seeks testimony about individual bonus and incentive compensation contests implemented over a period of nearly

twenty years. No witness could reasonably be prepared to testify on this Topic at a high level of detail, and Janssen will not provide a witness to do so here.

Subject to and without waiving the foregoing objections, Janssen will provide a written response to questions concerning this Topic.

TOPIC NO. 17 (as amended June 24, 2024):

The corporate organization and responsibilities of the departments, groups, and teams (such as sales, marketing, legal, compliance, regulatory, analytics, sales training, and finance) who had significant involvement in the strategy to provide the IOI Support to IOI Customers.

Relevant time period: From 2010 to until February 19, 2016.

RESPONSE TO TOPIC NO. 17:

Janssen objects that this Topic is overly broad, unduly burdensome, not proportional to the needs of the case, and exceeds the scope of discoverable matters under Federal Rule of Civil Procedure 26.

Janssen further objects to this Topic to the extent it is cumulative and seeks information that is duplicative of what is contained in the documents or written discovery that Janssen has already produced.

Janssen further objects to this Topic on the ground that it is vague, ambiguous, and overbroad and does not describe with reasonable particularity the matters on which examination is requested as required by Fed. R. Civ. P. 30(b)(6). For example, the terms “departments,” “groups,” “teams,” “significant involvement,” and “strategy” are not defined terms, are overbroad, and are reasonably subject to multiple interpretations. Further, by its terms, this Topic seeks expansive testimony about the corporate organization of Janssen throughout the time period identified. No witness could reasonably be prepared to testify on this Topic at a high level of detail, and Janssen will not provide a witness to do so here.

Subject to and without waiving the foregoing objections, Janssen will provide a witness to testify on this Topic.

Dated: July 22, 2024

s/ Jason C. Raofield

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document has been served by electronic mail on July 22, 2024, to the following counsel of record:

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